PTO/SB/21 (01-08)
Approved for use through 01/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	44

Application Number	10/662,906-Conf. #1268
Filing Date	September 15, 2003
First Named Inventor	Rong-Hwa Lin
Art Unit	1644
Examiner Name	P. Gambel
Attorney Docket Number	A0871.70001US00

ENCLOSURES (*Check all that apply*)

- [x] Fee Transmittal Form
  - [x] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [x] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please Identify below):

Copy of 1/29/08 Office Action for U.S. Application Serial No. 10/051,497
Copy of 12/12/07 Office Action for U.S. Application Serial No. 11/125,837
Check for $180.00
Return Receipt Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	WOLF, GREENFIELD & SACKS, P.C.		
Signature			
Printed name	Alan W. Steele, M.D., Ph.D.		
Date	February 7, 2008	Reg. No.	45,128

Certificate of Mailing Under 37 CFR 1.8(a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: February 7, 2008 Signature: _____ (Alan W. Steele, M.D., Ph.D.)

PTO/SB/17 (10-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2008

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($) 180.00

Complete if Known	
Application Number	10/662,906-Conf. #1268
Filing Date	September 15, 2003
First Named Inventor	Rong-Hwa Lin
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Art Unit	1644
Attorney Docket No.	A0871.70001US00

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☐ Deposit Account Deposit Account Number: 23/2825 Deposit Account Name: Wolf, Greenfield & Sacks, P.C.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fees Paid ($)**
Utility	310	155	510	255	210	105	
Design	210	105	100	50	130	65	
Plant	210	105	310	155	160	80	
Reissue	310	155	510	255	620	310	
Provisional	210	105	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	**Fee ($)**	**Small Entity Fee ($)**
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	210	105
Multiple dependent claims	370	185

Total Claims	**Extra Claims**	**Fee ($)**	**Fee Paid ($)**
_____ - 20 =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	**Extra Claims**	**Fee ($)**	**Fee Paid ($)**
_____ - 3 =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims

Fee ($)	**Fee Paid ($)**
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $260 ($130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	**Extra Sheets**	**Number of each additional 50 or fraction thereof**	**Fee ($)**	**Fee Paid ($)**
_____ - 100 =	_____	/50 = _____ (round up to a whole number) x	_____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement	180.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 45,128	Telephone 617.646.8000
Name (Print/Type)	Alan W. Steele, M.D., Ph.D.		Date February 7, 2008

Certificate of Mailing Under 37 CFR 1.8(a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: February 7, 2008 Signature: _____ (Alan W. Steele, M.D., Ph.D.)

DOCKET NO.: A0871.70001US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rong-Hwa Lin et al.
Serial No.:	10/662,906
Confirmation No.:	1268
Filed:	September 15, 2003
For:	MODULATORS OF P-SELECTIN GLYCOPROTEIN LIGAND 1
Examiner:	Phillip Gambel
Art Unit:	1644

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 7th day of February, 2008.

Alan W. Steele, M.D., Ph.D., Reg. No. 45,128

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 C.F.R. §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office action, but before the mailing date of any final action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of $180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

02/11/2008 CCHAU1 00000055 10662906
01 FC:1806 180.00 OP

PART II: Information Cited

The Applicant would like to bring to the Examiner's attention the enclosed Office Action dated 12/12/07 from co-pending application Serial No. 11/125,837.

The Applicant would also like to bring to the Examiner's attention the enclosed Office Action dated 1/29/08 from co-pending Application Serial No. 10/051,497.

These two Office Actions include provisional obviousness-type double patenting rejections concerning at least one claim in instant Application Serial No. 10/662,906.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

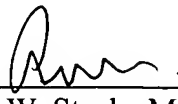
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

Dated: February 7, 2008

By: 

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/125,837	05/10/2005	Rong-Hwa Lin	A0871.70002US01	2174

23628 7590 12/12/2007
WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/125,837	LIN ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7,9,11-18 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7,9,13-15, 17 and 31* is/are rejected.

7)☒ Claim(s) *11,12,16,18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice to Comply with Sequence Rules.

Application No. 11/145,857

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☒ 7. SEE OFFICE ACTION

Other: _____

Applicant must provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123
For CRF submission help, call (703) 308-4212
For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.

DETAILED ACTION

1. Applicant's amendment, filed 11/23/2007, has been entered.

Claims 1, 3, 5, 7, 9, 12 and 17 have been amended.

Claims 2, 4, 6, 8, 10 and 19-30 have been canceled.

Claim 31 has been added.

Claims 1, 3, 5, 7, 9, 11-18 and 31 are pending.

2. Applicant's provisional election of Group 1 and species of PSGL-1-specific antibody humanized 15A7 (including SEQ ID NOS 1-6 and 25-26) in the Response to Restriction Requirement, filed 10/15/2007.

Given the cancellation of claims drawn to the methods of Group II in the Restriction Requirement, mailed 09/12/2007;
the previous Restriction Requirement has been rendered moot.

Therefore, claims 1, 3, 5, 7, 9, 11-18 and 31 are pending and being acted upon herein.

3. With respect to applicant's amending the specification to correct the sequence of Hu15A7 (with "L" instead of "S"),
it appears that the error and the correction are obvious.

Therefore, applicant's correction is not New Matter with respect to the provisions of 35 USC 112, first paragraph, written description..

However, the Sequence Listing and the corresponding computer readable form are not consistent with applicant's amendment of the instant specification to provide for this correction of the sequence of Hu15A7.

Therefore, this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, the paper copy and the CRF submission fail to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Further, applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Applicant is required to review the instant application carefully for compliance with the Sequence Rules and that there is consistency between the specification and the Sequence Listing and CRF.

4. Priority.

Given that the support for correcting the sequence of Hu15A7 (with "L" instead of "S") appears to be provided in the priority application USSN 60/569,892, filed 05/10/2004, even though no Sequence Listing nor CRF were provided;

The effective filing date of the instant claims is deemed to be the filing date of the priority application USSN 60/569,892, filed 05/10/2004.

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

6. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected. Appropriate corrections are required.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate corrections are required

7. Claim 3 is objected because "or 26" should be "26".

8. Claim 13-15 and 31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 13-15 are indefinite in the recitation of "amino acid residues" in the absence of either a specific sequence to those residues or to a reference sequence by which one can determine the amino acid sequence.

Applicant is invited to amend the claims to recite appropriate sequences or a reference SEQ ID NO. for the recited amino acid residues.

B) Claim 31 is indefinite in the recitation of "15A7" because its characteristics are not known. The use of humanized "15A7" antibody as the sole means of identifying the claimed antibody renders the claim indefinite because "15A7" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation s to define completely distinct hybridomas / cell lines.

Applicant is invited to provide all of the appropriate SEQ ID NOS. that read on the entire 15A7 antibody or the humanized 15A7 antibody.

Alternatively, applicant is invited to provide the appropriate Accession Number in conjunction with satisfying the enablement requirements for the deposit of biological materials addressed below in the rejection under 35 USC, 112, first paragraph.

C) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3, 5, 7 and 31 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

A) Antibodies in the absence of an antigen specificity: Claims 1, 3, 5, 7.

Antibodies are glycoproteins that possess the ability to react in vitro and in vivo specifically and selectively with the antigenic determinants or epitopes eliciting their production or with an antigenic determinant closely related to the homologous antigen. Antibodies are immunoglobulins that are formed in response to immunogens or that are screened for specificity an antigen / immunogen.

It has been well established in the art that the antigen binding specificity is critical to how the skilled artisan would employ antibodies in various modalities (e.g., affinity purification, detection or diagnostic assays, bioassays, treatment), including those consistent with the instant disclosure (see specification, including the Summary of the Invention and pages 11-13).

However, the instant claims do not recite an antigen specificity for PSGL-1 or human PSGL-1.

The specification provides insufficient direction or guidance regarding how to use antibodies or immunoglobulin chains comprising the claimed sequences *in the absence of an antigen specificity for (human) PSGL-1* and yet retain substantially the same binding specificity of the anti-PSGL-1 antibodies, which are enabling consistent with the disclosed utilities of the instant disclosure (see Summary of the Invention and pages 11-3 of the instant specification).

Given the well known polymorphism of antibodies, it would have been undue experimentation to make and use the vast repertoire of antibodies and immunoglobulin chains encompassed by the claimed invention in the absence of binding specificity for PSGL-1 to enable the scope of the claimed antibodies encompassed by the claimed invention.

Without sufficient guidance and given the well known complexity and unpredictability of using antibodies and immunoglobulin chains with no particular antigen specificity as well the well known polymorphism of antibodies; it would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue to make and use the vast repertoire of antibodies broadly encompassed by the claimed invention in order to make and use the anti-PSGL-1 antibodies consistent with the instant disclosure.

Applicant is invited to amend the claims to recite the appropriate antigen specificity to obviate this rejection.

B) Anti-PSGL-1 Antibodies lacking an entire variable heavy of light chain or all six (6) CDRs: Claim 1.

With respect to claims that recite anti-PSGL-1 antibodies and immunoglobulin chains that comprise particular CDRs (but not six CDRs or an entire variable heavy and/or light chains with antigen specificity to PSGL-1),

the instant claims encompass anti-PSGL-1 antibodies and immunoglobulin chains that do not comprise sufficient structural elements to provide for antibodies to provide for the antigen specificity of PSGL-1 as broadly encompassed by the claimed invention.

It has been well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity, which is characteristic of the parent immunoglobulin. All of the heavy and light chain CDRs should be in their proper order and in the context of framework sequences which maintain their required conformation in order to provide a binding molecule having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites.

Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al (Proc Natl Acad Sci USA 79: 1979-1983 (1982). Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function.

Single amino changes to either a CDR or even in certain circumstances to the framework can result in decrease affinity of antigen or even ablation of antibody binding and specificity.

Also, see the teachings of Colman (Research in Immunology 145: 33-36, 1994) on the effects of amino acid sequence changes on antibody-antigen interactions.

While being enabling for the PSGL-1-specific antibodies comprising the claimed sequences derived from the disclosed "15A7 antibody" comprising an entire variable heavy or light chain or all six (6) CDRs, as set forth in the instant claims and disclosed in the specification as filed, does not reasonably provide enablement for any "antibody" or "immunoglobulin chain" broadly encompassed by the claimed invention.

It is unlikely that any "antibody or immunoglobulin chain" broadly encompassed by the claimed invention as defined by the claims will have the required binding function for PSGL-1 and, in turn, have the required therapeutic properties encompassed by the "pharmaceutical compositions" encompassed by the claimed invention and described in the specification as well.

The specification provides insufficient direction and guidance regarding how to produce any "antibody or immunoglobulin chain" broadly encompassed by the claimed invention.

Undue experimentation would be required to produce the invention commensurate with the scope of the claims from the instant disclosure alone. One of skill in the art would neither expect nor predict the appropriate functioning of the claimed "antibodies and immunoglobulin chains" thereof as broadly as is claimed. Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

Without sufficient guidance, the breadth of incomplete structures or antigen specificity defined in the claimed "antibodies and immunoglobulin chains" and still provide or maintain sufficient binding or activity (e.g., induction of cell death of activated T cells) would have been unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Applicant is invited to amend the claims to limit to PSGL-1-specific antibodies that comprise either those particular SEQ IDS NOS. (e.g., an entire variable heavy and/or light chain or all six (6) CDRs) that define the instant "15A7" PSGL-1-specific antibodies disclosed in the specification as filed in order to obviate this rejection.

C) Humanized 15A7. Claim 31.

It is apparent that the humanized 15A7 or 15A7 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Alternatively, applicant may amend claim 31 to recite the appropriate SEQ ID NOS. that define the "humanized 15A7 antibody" in order to obviate this objection/rejection.

It is noted that the sequence of an entire immunoglobulin satisfies the biological deposit of said immunoglobulin.

Note that satisfaction for the biological deposit of the specific humanized 15A7 or 15A7 antibody requires the disclosure and recitation of its entire amino acid sequence and not based upon partial sequences.

Further, it is noted that the claim 31 is drawn to the "humanized 15A7 antibody".

Therefore, the appropriate sequences should read on the "humanized 15A7 antibody".

If the claim were to read on "a humanized antibody *derived from 15A7*", then the appropriate sequences for the "15A7 antibody" would be required.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 9, 13-15 and 17 are rejected under 35 U.S.C. § 102 (e) as anticipated by Lazarovits et al. (US 2004/0002450) (see entire document).

Lazarovits et al. teach PSGL-1-specific antibodies, including antibodies that bind sialylated and fucosylated structures that are required for binding to P-selectin and L-selectin, including the tyrosine sulfation of the amino-terminal region of PSGL-1 (see Selectins and PSGL-1 in paragraphs [0029] – [0042].

Here, Lazarovits et al. also teach the anti-PSGL-1 antibodies KPL1, Y1 and Y17 (e.g. see Background of the Invention, including paragraph [0036] Summary of the Invention, including paragraphs [0017] and [0144; Detailed Description of the Invention, including paragraphs [0235] – [0245], [0298] -] ;] anti

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention in that the claimed functional limitations of "binding PSGL-1 without interfering with binding PSGL-1 and P-selectin", upon binding on an activated T cells, induces death of the activated T cell" as well as the amino residues recited in claims 13-15.

The products of the instant claims and the prior art are defined in terms of physical characteristics. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons.

It is the burden of the applicant to show the unobvious difference between the claimed and disclosed antibodies and compositions.

Also, the Courts have held that there is no requirement that those of ordinary skill in the art know of the inherent property. See MPEP 2131.01(d) and MPEP 2112 - 2113 for case law on inherency.

14. Claims 9, 13-15 and 17 are rejected under 35 U.S.C. § 102 (e) as anticipated by Levanon et al. (US 2004/0001839) (see entire document).

Levanon et al. teach PSGL-1-specific antibodies (e.g., see entire document, including paragraphs [0055] – [0057]; Summary of the Invention on paragraphs [0059] – [0144]; Detailed Description of the Invention), including the Y1, Y17 and KPL1 epitopic specificities (e.g., see Selectins and PSGL-1 on paragraphs [0029] – [0042]; Summary of the Invention; Detailed Description of the Invention; and Examples), including antibody constructs (e.g., see paragraphs [0448] – [0493]), including multivalent or multimeric antibody constructs (e.g., see paragraphs [0047] – [0052], Summary of the Invention on paragraphs [0059] – [117], [0454], [0459] – [0493]; Examples 8 – 16 on pages 36-38).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention in that the claimed functional limitations of "binding PSGL-1 without interfering with binding PSGL-1 and P-selectin", upon binding on an activated T cells, induces death of the activated T cell" as well as the amino residues recited in claims 13-15.

The products of the instant claims and the prior art are defined in terms of physical characteristics. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons.

It is the burden of the applicant to show the unobvious difference between the claimed and disclosed antibodies and compositions.

Also, the Courts have held that there is no requirement that those of ordinary skill in the art know of the inherent property. See MPEP 2131.01(d) and MPEP 2112 - 2113 for case law on inherency.

15. Claim 9, 13-15 and 17 are rejected under 35 U.S.C. § 102 (e) as anticipated by Lin et al. (US 2003/0049252) (see entire document).

Lin et al. teach PSGL-1-specific antibodies, including antibodies that can induce the depletion and/or apoptosis of T cells (e.g., see entire document, including the Summary of the Invention, Detailed Description of the Invention and Claims), including the KPL1 epitopic specificity (e.g., see Anti-PSGL-1 Antibodies on paragraphs [0029] – [0042]; Screening Assays for Compounds on paragraphs [0049] – [0062]; that Modulate PSGL-1 Function on paragraphs 0063] – [0076] and Examples on paragraphs [0086] – [00125].

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention in that the claimed functional limitations of "binding PSGL-1 without interfering with binding PSGL-1 and P-selectin", upon binding on an activated T cells, induces death of the activated T cell" as well as the amino residues recited in claims 13-15.

The products of the instant claims and the prior art are defined in terms of physical characteristics. Comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons.

It is the burden of the applicant to show the unobvious difference between the claimed and disclosed antibodies and compositions.

Also, the Courts have held that there is no requirement that those of ordinary skill in the art know of the inherent property. See MPEP 2131.01(d) and MPEP 2112 - 2113 for case law on inherency.

16. Claim 9, 13-15 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable Lin et al. (US 2003/0049252) (see entire document).

Lin et al. teach PSGL-1-specific antibodies, including antibodies that can induce the depletion and/or apoptosis of T cells (e.g., see entire document, including the Summary of the Invention, Detailed Description of the Invention and Claims), including the KPL1 epitopic specificity (e.g., see Anti-PSGL-1 Antibodies on paragraphs [0029] – [0042]; Screening Assays for Compounds on paragraphs [0049] – [0062]; that Modulate PSGL-1 Function on paragraphs 0063] – [0076] and Examples on paragraphs [0086] – [00125].

Although Lin et al. does not teach the particular claimed limitations of "binding PSGL-1 without interfering with binding PSGL-1 and P-selectin", upon binding on an activated T cells, induces death of the activated T cell" as well as the amino residues recited in claims 13-15 per se,

Lin et al. does teach Screening Assays for Compounds on paragraphs [0049] – [0062]; that Modulate PSGL-1 Function on paragraphs 0063] – [0076] and Examples on paragraphs [0086] – [00125] as well as means for producing antibodies of interest (e.g., see Anti-PSGL-1 Antibodies on paragraphs [0029] – [0042]),

wherein the screening assays which are based upon binding PSGL-1 and the induction of T cell apoptosis in vitro or in vivo (e.g., see paragraphs [0051], [0057], [0069] and [0076] as well as Examples 1 and 10 and Claims).

Therefore, Lin et al. is not limited to teaching anti-PSGL-1 antibodies that induce T cell apoptosis but necessarily inhibit the binding of P-selectin to PSGL-1.

Given the long known success in selecting for antibodies to antigens and functional properties of interest in the antibody art

as well as the clear teaching of selecting for antibodies that bind PSGL-1 which can induce T cell apoptosis in the absence of inhibiting the binding of P-selectin to PSGL-1 and the exemplification of the TAB4 antibody to mouse PSGL-1 with this property,

the ordinary artisan would have been motivated to select for those PSGL-1-specific antibodies that bound human PSGL-1 and induced apoptosis of human T cells with an expectation of success at the time the invention was made.

It is proper to "take account of the inferences and creative steps that a person of ordinary skill in the art would employ". See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396 (2007).

One of ordinary skill in the art at the time the invention was made would have been motivated to provide anti-PSGL-1 antibodies, including multimeric antibodies comprising anti-PSGL-1 antibodies, including those anti-PSGL-1 antibodies with the Y1, Y17 and KPL1 epitopic specificities, and/or antibodies that bind PSGL-1 which can induce T cell apoptosis in the absence of inhibiting the binding of P-selectin to PSGL-1, given the exemplification of the TAB4 antibody to mouse PSGL-1 with this property, in the derivation of anti-PSGL-1 antibodies for the various utilities taught by the prior art at the time the invention was made.

A person of ordinary skill in the art at the time the invention was made would have been motivated by taking the advantages of the specificities and properties of the highly inhibitory properties of the Y1, Y17 and KPL1 anti-PSGL-1 antibody epitopic specificities, including their multimeric forms, as well as antibodies that bind PSGL-1 which can induce T cell apoptosis in the absence of inhibiting the binding of P-selectin to PSGL-1 and the exemplification of the TAB4 antibody to mouse PSGL-1 with this property, to treat various inflammatory, autoimmune and cancer conditions with an expectation of success, since such properties and advantages are consistent with human therapeutic regimens associated with treating said conditions at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to provide antagonistic anti-PSGL-1 antibodies to treat a variety of inflammatory, autoimmune and cancer conditions,

incorporating antibodies that bind PSGL-1 which can induce T cell apoptosis in the absence of inhibiting the binding of P-selectin to PSGL-1 and the exemplification of the TAB4 antibody to mouse PSGL-1 with this property for use in various therapeutic utilities would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing therapeutic anti-PSGL-1 antibodies at the time the invention was made.

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 9, 13-15 and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable
over claim 39 of USSN 10/662,906
in view of Lazarovits et al. (US 2004/0002450 A1) (1449; #A17) AND/OR Levanon et al. (US 2004/0001839 A1) and the well known convention in the art at the time the invention was made to place therapeutic components, including therapeutic antibodies, in a kit for convenience and economy, as evidenced by Anderson et al. (U.S. Patent No. 6,348,581) AND/OR Hockfield et al. (U.S. Patent No. 6,884,619) for the reasons above in Section 6.

The copending claims differ from the instant claims by not reciting multimeric anti-PSGL-1 antibodies per se and providing said anti-PSGL-1 antibodies in kits comprising said multimeric anti-PSGL-1 antibodies and instructions for use.

However, the single chain and/or multimeric anti-PSGL-1 antibodies are either encompassed or would have been obvious variants in the construction of anti-PSGL-1 antibodies at the time the invention was made, given their antagonistic properties as well as being consistent with the disclosures of the instant and copending specificaitons.

19. Claim 9, 13-15 and 17 are directed to an invention not patentably distinct from claim 39 of commonly assigned USSN 10/662,906 for the reasons set forth above in Section 17.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned USSN 10/662,906, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

20. No claim allowed.

It is noted that the claims drawn to the humanized 15A7 antibodies appear to be free of the prior art.

Claims 11-12, 16 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, Ph.D., J.D.
Primary Examiner
Technology Center 1600
December 10, 2007

FORM PTO-1449/A and B (modified PTO/SB/08)	APPLICATION NO.: 11/125,837	ATTY. DOCKET NO.: A0871.70002US01
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: May 10, 2005	CONFIRMATION NO.: 2174
	APPLICANT: Rong-Hwa Lin et al.	
Sheet 1 of 1	GROUP ART UNIT: 1644	EXAMINER: Phillip Gambel

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
PG	C35	CO MS et al., Properties and pharmacokinetics of two humanized antibodies specific for L-selectin. *Immunotechnology.* 1999 Mar;4(3-4):253-66.	

EXAMINER:	DATE CONSIDERED:
Phillip Gambel	11/6/07

EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

a copy of this reference is not provided as it was previously citedby or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

FORM PTO-1449/A and B (modified PTO/SB/08)	APPLICATION NO.: 11/125,837	ATTY. DOCKET NO.: A0871.70002US01
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: May 10, 2005	CONFIRMATION NO.: 2174
	APPLICANT: Rong-Hwa Lin et al.	
Sheet 1 of 4	GROUP ART UNIT: 1644	EXAMINER: Phillip Gabel

U.S. PATENT DOCUMENTS

Examiner's Initials*	Cite No.	U.S. Patent Document Number	U.S. Patent Document Kind Code	Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
PG	A1	5,378,464		McEver	01-03-1995
	A2	5,618,785		Heavner et al.	04-08-1997
	A3	5,709,859		Aruffo et al.	01-20-1998
	A4	5,710,123		Heavner et al.	01-20-1998
	A5	5,808,025		Tedder et al.	09-15-1998
	A6	5,827,817		Larsen et al.	10-27-1998
	A7	5,834,425		Tedder et al.	11-10-1998
	A8	5,840,679		Larsen et al.	11-24-1998
	A9	5,843,707		Larsen et al.	12-01-1998
	A10	5,852,175		Cummings et al.	12-22-1998
	A11	5,972,625		Rosen et al.	10-26-1999
	A12	6,056,956		Cobbold et al.	05-02-2000
	A13	6,124,267		McEver et al.	09-26-2000
	A14	6,309,639		Cummings et al.	10-30-2001
	A15	2002-0164336	A1	Harrison et al.	11-07-2002
PG	A16	6,667,036		Cummings et al.	12-23-2003

FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No.	Foreign Patent Document Office/ Country	Foreign Patent Document Number	Foreign Patent Document Kind Code	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
PG	B1	WO	97/06176		Board of Regents of Univ. of Oklahoma	02-20-1997	
PG	B2	WO	00/25808	A1	Genetics Institute, Inc.	05-11-2000	
PG	B3	WO	03/013603	A1	AbGenomics Corp.	02-20-2003	

EXAMINER:	DATE CONSIDERED:
Phillip Gabel 12/6/07	

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FORM PTO-1449/A and B (modified PTO/SB/08)	APPLICATION NO.: 11/125,837	ATTY. DOCKET NO.: A0871.70002US01
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: May 10, 2005	CONFIRMATION NO.: 2174
	APPLICANT: Rong-Hwa Lin et al.	
Sheet 2 of 4	GROUP ART UNIT: 1644	EXAMINER: Phillip Gambel

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
PG	C1	BATTISTINI et al., "CD8+ T cells from 1-37 patients with acute multiple sclerosis display selective increase of adhesiveness in brain venules: A critical role for P-selectin glycoprotein ligand-1." *Blood*, Vol. 101, No. 12, 4775-4782 (June 15, 2003).	
	C2	BECKWITH et al., "The Protein Product of the Proto-oncogene c-cbl Forms a Complex With Phosphatidylinositol 3-Kinase p85 and CID 19 in Anti-IgM Stimulated Human B-Lymphoma Cells," *Blood* 88(9):3502-3507, (1996).	
	C3	BESNAULT et al., "B Cell Receptor Cross-Linking Triggers a Caspase-8-Dependent Apoptotic Pathway That Is Independent of the Death Effector Domain of Fas-Associated Death Domain Protein," *J. Immunol.*, 167:733-740, (2001).	
	C4	BORGES et al., "P-Selectin Glycoprotein Ligand-1 (PSGL-1) on T Helper 1 but Not on T Helper 2 Cells Binds to P-Selectin and Supports Migration into Inflamed Skin," *J. Exp. Med.* 185(3):573-578 (February 3, 1997).	
	C5	BORGES et al., "The Binding of T Cell-expressed P-selectin Glycoprotein Ligand-1 to E- and P-selectin Is Differentially Regulated," *J. Biol. Chem.* 272(45):28786-28792 (November 7, 1997).	
	C6	CHEN SC et al., Cross-linking of P-selectin glycoprotein ligand-1 induces death of activated T cells. *Blood.* 2004 Nov 15;104(10):3233-42. Epub 2004 Jun 15.	
	C7	DIACOVO et al., "Interactions of human alpha/beta and gamma/delta T lymphocyte subsets in shear flow with E-selectin and P-selectin." *J. Exp. Med.*, Vol. 183, 1193-1203 (March 1996).	
	C8	DIMITROFF et al., "Glycosylation-dependent inhibition of cutaneous lymphocyte-associated antigen expression: Implications in modulating lymphocyte migration to skin." *Blood*, Vol. 101, No. 2, 602-610 (January 15, 2003).	
	C9	EVANGELISTA et al., "Platelet/Polymorphonuclear Leukocyte Interaction: P-Selectin Triggers Protein-Tyrosine Phosphorylation-Dependent CD11b/CD 18 Adhesion: Role ofPSGL-1 as a Signaling Molecule," *Blood* 93(3):876-885 (February 1, 1999).	
	C10	FARADAY et al., "Leukocytes Can Enhance Platelet-mediated Aggregation and Thromboxane Release via Interaction of P-selectin Glycoprotein Ligand 1 with P-selectin," *Anesthesiology* 94(1):145-151 (January 2001).)	
	C11	FRENETTE et al., "P-Selectin Glycoprotein Ligand 1 (PSGL-1) Is Expressed on Platelets and Can Mediate Platelet-Endothelial Interactions In Vivo," J. *Exp. Med.* 191(8):1413-1422 (April 17, 2000).	
	C12	FUHLBRIGGE et al., "Cutaneous lymphocyte antigen is a specialized form of PSGL-1 expressed on skin-homing T cells," *Nature* 389:978-981 (October 1997).	
PG	C13	HERRON MJ et al., Intracellular parasitism by the human granulocytic ehrlichiosis bacterium through the P-selectin ligand, PSGL-1. *Science.* 2000 Jun 2;288(5471):1653-6.	

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Phillip Gambel 12/6/07	

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FORM PTO-1449/A and B (modified PTO/SB/08)	APPLICATION NO.: 11/125,837	ATTY. DOCKET NO.: A0871.70002US01
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: May 10, 2005	CONFIRMATION NO.: 2174
	APPLICANT: Rong-Hwa Lin et al.	
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	C14	HIRATA et al., "P-Selectin Glycoprotein Ligand 1 (PSGL-1) Is a Physiological Ligand for E-Selectin in Mediating T Helper 1 Lymphocyte Migration," *J. Exp. Med.* 192(11):1669-1675 (December 4, 2000).	
	C15	HIROSE et al., "A functional epitope on P-selectin that supports binding of P-selectin to P-selectin glycoprotein ligand-1 but not to sialyl Lewis X oligosaccharides," *Internatl. Immunol.* 10(5):639-649 (January 26, 1998).	
	C16	IGARASHI et al., "Telomerase Activity Is Induced in Human Peripheral B Lymphocytes by the Stimulation to Antigen Receptor," *Blood*, 89(4):1299-1307, (1997).	
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	C24	SHAN et al., "Apoptosis of Malignant Human B Cells by Ligation of CD20 With Monoclonal Antibodies," *Blood*, 91(5):1644-1652, (1998)	
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EXAMINER: Phillip Gambel 11/6/07	DATE CONSIDERED:

[1] EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

FORM PTO-1449/A and B (modified PTO/SB/08)	APPLICATION NO.: 11/125,837	ATTY. DOCKET NO.: A0871.70002US01
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: May 10, 2005	CONFIRMATION NO.: 2174
	APPLICANT: Rong-Hwa Lin et al.	
Sheet 4 of 4	GROUP ART UNIT: 1644	EXAMINER: Phillip Gambel

MS*	C30	WING et al., "Mechanism of First-Dose Cytokine-Release Syndrome by CAMPATH 1-H: Involvement of CD16 (FcγRIII) and CD11a/CD18 (LFA-1) on NK Cells," *J. Clin. Invest.* 98(12):2819-2826 (1996).	
	C31	WOLTMANN et al., "Interleukin-13 induces PSGL-1/P-selectin-dependent adhesion of eosinophils, but not neutrophils, to human umbilical vein endothelial cells under flow." *Blood*, Vol. 95, No. 10, 3146-3152 (May15, 2000).	
	C32	WU et al., "Role of P-Selectin and Anti-P-Selectin Monoclonal Antibody in Apoptosis During Hepatic/Renal Ischemia Reperfusion Injury," *World J. Gastroentero* 6(2):244-247 (2000).	
	C33	YAGO et al., "IL-12 Promotes the Adhesion of NK Cells to Endothelial Selectins Under Flow Conditions," *J. Immunol.* 161:1140-1145 (1998).	
MS*	C34	YANG et al., "Targeted Gene Disruption Demonstrates That P-Selectin Glycoprotein Ligand 1 (PSGL-1) Is Required for P-Selectin-mediated but Not E-Selectin-mediated Neutrophil Rolling and Migration," *J. Exp. Med.* 190(12):1769-1782 (December 20, 1999).	

EXAMINER:	DATE CONSIDERED:
Phillip Gambel 12/6/07	

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

Notice of References Cited	Application/Control No. 11/125,837	Applicant(s)/Patent Under Reexamination LIN ET AL.	
	Examiner Phillip Gambel	Art Unit 1644	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2004/0002450	01-2004	Lazarovits et al.	514/12
*	B	US-2004/0001839	01-2004	Levanon et al.	424/178.1
*	C	US-2003/0049252	03-2003	Lin et al.	424/144.1
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Rudikoff et al. Proc Natl Acad Sci USA 79: 1979-1983,1982.
	V	
	W	Colman, Research in Immunology 145: 33-36, 1994.
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,497	01/18/2002	Rong-Hwa Lin	A0871.70000US01	1774

23628 7590 01/29/2008
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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
01/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/051,497	LIN ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-9,11-13,17,19,20,22-25 and 38* is/are pending in the application.

4a) Of the above claim(s) *7-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,11-13,17,19,20,22-25 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. ACKNOWLEDGE STATEMENT
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FILED 1/29/08

DETAILED ACTION

1. Applicant's amendment, filed 10/24/2007, has been entered.

Claims 1, 3, 4, 11, 12, 17, 19, 20, 22-25 and 38 have been amended.

Claim 10 has been canceled.
Claims 2, 5, 14-16, 18, 21, and 26-37 have been canceled previously.

Claims 1, 3, 4, 6-9, 11-13, 17, 19, 20, 22-25 and 38 are pending.

As pointed out previously, applicant's election of species (B), drawn to methods using an anti-PSGL-1 antibody and an agent that binds to the antibody and induces the cross-linking of a plurality of PSGL-1 antigens on the cell surface without traverse in the Reply, filed 07/22/2004, and the species autoimmune disease and type I diabetes in the Reply, filed 03/10/2004, has been acknowledged.

Claims 1, 3, 4, 6, 11-13, 17, 19, 20, 22-25 and 38 are under consideration in the instant application.

Claims 7-9 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected invention or species.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's amendment, filed 10/24/2007.

The rejections of record can be found in the previous Office Action.

3. Priority.

Applicant submits that the applicant has previously addressed this issue and respectfully disagrees, but acknowledges the examiner's argument of record.

The following is reiterated for applicant's convenience.

As indicated previously, the filing date of the instant claims is deemed to be the filing date of the instant application USSN 10/051,497, filed 01/18/2002;
as the previous provisional priority application USSN 60/310,196, filed 08/03/2001, does not appear to provide sufficient written description for the claimed "limitations".

Applicant's assertions, filed 02/01/2007, concerning the priority of the instant invention back to priority USSN 60/310,196, filed 8/3/01, are acknowledged.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

As indicated in the previous Office Action, mailed 07/31/2006,
these assertions have not been found convincing essentially for the reasons of record reiterated herein for applicant's convenience.

As indicated previously, the instant claims now recite limitations which were not clearly disclosed in the priority provisional application as well as the specification as-filed, and would have changed the scope of the priority application and do change the scope of the instant disclosure as-filed.

For example, it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Therefore, applicant's reliance on generic methods to reduce T cell-mediated immune responses with PSGL-1-specific antibodies and certain limitations found in the Examples of the provisional application does not provide sufficient written description for the claimed limitations indicated previously and herein, as currently claimed.

As indicated previously, the filing date of the instant claims as they read on "methods of preventing or reducing a T cell-mediated immune responses in an individual, including the "selecting an individual diagnosed", "administering a compound ... induces a signal transduction pathway that results in the death of the T cell" (e.g. claim 1), "an agent that binds to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigens on the surface of the T cell" (e.g. claim 4), detecting the number of T cells in a first biological sample (e.g. claims 13-14), "20% of peripheral blood $CD3^+$ cells (e.g. claims 15-16) and "diabetes" (e.g. elected autoimmune disease) is deemed to be the filing date of the instant application USSN 10/051,497, filed 8/3/01, as the previous provisional priority application does not appear to provide sufficient written description for the claimed "limitations" indicated herein.

Here, with respect to the recitation of "detecting the number of T cells in a first biological sample",

applicant relies upon Example 6 of the provisional application USSN 60/310,196, filed 08/03/2001 and likewise Example 6 of the instant application, USSN 10/051,497 to support the description above, via the administration of an anti-PSGL antibody TAB4 to experimental mice, measuring the percentage of $CD3^+$ T cells in harvested spleen and peripheral blood and comparing these results with corresponding results from untreated mice.

Applicant continues to assert that this comparison of control and treated mice is tantamount to what is claimed in claim 13.

However, as pointed out previously, applicant is relying upon a limited experimental study measuring certain parameters under certain defined conditions, while the claims are broader in scope or breadth.

It is acknowledged that page 15, lines 14-20 of the provisional application USSN 60/310,196, filed 08/03/2001, provides written description for targeting "diabetes mellitus" with anti-TAIP compounds (i.e., anti-PSGL-1 compounds)

Although applicant disagrees with this analysis, applicant has not presented a convincing detailed analysis as to why the claimed subject matter has clear support in the parent application, other than to assert that the provisional application provides ample written description for each and every limitation as presented and citing certain passages of the provisional application without sufficiently pointing out written support for the "limitations" indicated previously and herein.

Again, applicant is invited to verify the priority date of the instant claims, including written support and enablement under 35 USC 112, first paragraph.

Again, if applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the parent application. Applicant is invited to verify the priority date of the instant claims, including written support and enablement under 35 USC 112, first paragraph.

4. This is a rejection under 35 USC § 112, first paragraph, "new matter".

Claims 4 and 20 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed:

"an antibody that binds to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigen on the surface of the T cell".

Applicant's arguments, filed 10/24/2007, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

As indicated in the previous Office Actions, mailed 07/31/2006 and 04/19/2007; these assertions have not been found convincing essentially for the reasons of record reiterated herein for applicant's convenience.

Again, it appears that applicant continues to rely upon the disclosure of the anti-hamster Ig as a cross-linker antibody (e.g. see Example 3 on pages 19-20) to support an entire (sub)genus of "antibodies that bind to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigen on the surface of the T cell".

In addition, applicant again points out that Example 10 discloses another antibody, namely cross-linker rabbit anti-mouse Ig that binds to the monoclonal antibody and induces cross-linking of a plurality of PSGL-1 antigens on the surface of T cells or NK cells.

Therefore, applicant asserts that two (2) examples of cross-linking antibody as claimed have been disclosed.

Applicant also relies upon the original claims which recite "administering an agent that binds to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigens on the surface of the T cell or NK cell" to support the current claim recitation of "an antibody that bins to the monoclonal antibody and induces cross-linking of a plurality of PSGL-1 antigens on the surface of the T cell".

Applicant relies upon Lockwood v American Airlines, Inc., 107 F.3d, 1565 (Fed. Cir. 1997, Plfaff v. Wells Elecs., Inc., 525 U.S. 55, 68 (1998), Regents of the University of California v. Eli Lilly, 119 F.3d 1559 (Fed. Cir. 1997) and Vas-Cath Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991) to indicate that the limitations can be / must be supported in the specification through express, implicit or inherent disclosure and to show that applicant had possession of the claimed invention. Also, see MPEP 2163.

Also, applicant has asserted previously that rather than providing a generic or sub-generic disclosure, applicant provides a disclosure of a particular species of the claimed genus of cross-linking antibodies.

Again, and consistent with applicant's arguments;
applicant's reliance on a generic disclosure (e.g. agent) and limited species (e.g. anti-hamster Ig and rabbit anti-mouse Ig in Examples 3 and 10) does not provide sufficient direction and guidance to the generic "antibody that binds to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigen on the surface of the T cell", as currently claimed.

It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Applicant relies upon the ordinary artisan recognizing the possession of a subgenus of two Examples of cross-linking antibodies based upon certain Examples in the specification as-filed rather than clear written description of the claimed "limitation" in the application as filed and currently claimed.

Applicant has not provided sufficient direction either in the instant application as filed or in the priority application for
"an antibody that binds to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigen on the surface of the T cell" as currently claimed.

In addition, applicant further submits that it would be appreciated that the claimed genus of cross-linking antibodies includes any suitable anti-isotype antibody, examples of which are so numerous in the prior art.

However, applicant is relying upon in vitro Examples of testing antibodies to support in vivo treatment methods.

Obviousness is not the standard for the addition new limitations to the disclosure as filed.

It is noted that entitlement to a filing date does not extend to subject matter, which is not disclosed, but would be obvious over what is expressly disclosed.
See Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

In contradistinction to applicant's reliance upon certain legal decisions in conjunction with the Examples in the instant specification,
applicant's reliance upon the disclosure of the instant (and priority application) does not provide sufficient disclosure of a broad and complete disclosure coupled with extensive examples to fully support the current claimed recitation.

Again, the specification as filed does not provide a sufficient written description nor provide sufficient blaze marks nor direction for the instant methods encompassing the above-mentioned "limitation", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant's arguments have not been found persuasive.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above.
See MPEP 714.02 and 2163.06

5. With respect to the enablement rejection of record and that presented herein,
applicant's arguments, filed 10/26/2007, have been fully considered but have not been found convincing essentially for the reasons of record and addressed herein.

Without conceding the validity of the enablement rejection of record,
applicant submits that the claims have been amended to omit the phrase "antigen-binding fragments" to avoid the previous enablement rejection of record.

Again, given that the record, including the instant Examples, shows that cross-linking of PSGL-1 on cells appears to be required for the induction of apoptosis of activated T cells,
the enablement rejection of record is still deemed relevant to the current amended claims.

However, in addition to the enablement issues concerning
the claimed methods *to induce apoptosis in T cells and NK cells with PSGL-1-specific antigen-binding fragments in the absence of administering secondary cross-linking agents / antibodies*;
the following is added to the enablement rejection of record.

As an alternative to *administering secondary cross-linking agents / antibodies,*
It appears that *administering multivalent anti-PSGL-1 antibodies, such as diabodies,* would be an alternative in obtaining cross-linking of PSGL-1 on activated T cells surfaces resulting in apoptosis of said activated T cells.

6. Claims 1, 3, 4, 6-9, 11-13, 17, 19, 20, 22-25 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

In vitro and animal model studies have not correlated well with in vivo clinical trial results in patients. Since the therapeutic indices of immunosuppressive drugs or biopharmaceutical drugs can be species- and model-dependent, it is not clear that reliance on the in vitro and in vivo experimental observations as well as the clinical experience with targeting various inflammatory conditions with PSGL-1 specific antibodies accurately reflects the relative ability or efficacy of the claimed methods *to induce apoptosis in T cells and NK cells with PSGL-1-specific antigen-binding fragments in the absence of administering secondary cross-linking agents / antibodies or administering multivalent anti-PSGL-1 antibodies, such as diabodies.*

Pharmaceutical therapies in the absence of in vivo clinical data are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment.
See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

This invention encompasses administering any "anti-PSGL-1 antibody" to induce apoptosis in T cells and NK cells in the absence of administering cross-linking agents / antibodies or in the absence of administering multivalent anti-PSGL-1 antibodies (e.g., diabodies).

Applicant has indicated that the claimed methods rely upon secondary cross-linking agents / antibodies to accomplish the claimed mode of action (i.e., apoptosis),
whether or not the anti-PSGL-1 antibodies are administered even in the absence of cross-linking agents/antibodies or .
whether or not the anti-PSGL-1 antibodies are multivalent
(e.g., see page 13, lines 4-9 of Applicant's Remarks, filed 02/01/2007).

While applicant has acknowledged that Fc binding via Fc receptors *may* provide an additional mechanism of action that precludes the need for administering secondary cross-linking agents / antibodies,
such a mechanism of action relies upon the administration of anti-PSGL-1 antibodies that have the structural capacity to bind Fc receptors as well as the ability to cross-link PSGL-1 on the surface of activated T cells.

Further, the instant specification as-filed apparently provides limited direction and guidance as to appropriate secondary cross-linking agents / antibodies, namely "anti-hamster Ig" and "rabbit anti-mouse Ig" as "an antibody that bind to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigens on the surface of cell",

Also, the specification as-filed does not appear to provide for multivalent anti-PSGL-1 antibodies as an alternative to adding secondary cross-linking agents / antibodies in order to induce PSGL-1 on activated T cells in order to induce apoptosis on said T cells.

However, applicant has not provided sufficient direction and guidance in the specification as filed as how to make and to use such cross-linking antibodies in the claimed methods, as generically claimed.

Again as applicant acknowledged, applicant appears to be relying upon the disclosure of the anti-hamster Ig or rabbit anti-mouse Ig as a cross-linker antibody (e.g. see Example 3 on pages 19-20 and Example 10 on pages 26-27) to support an entire genus of "antibodies that bind to an anti-PSGL-1 antibody".

In contrast to the in vitro assays under controlled conditions set forth in the instant Example,
the instant specification does not provide sufficient direction and guidance as to the nature of antibodies that can induce cross-linking in vivo, broadly encompassed by the claimed invention.

The instant specification as-filed does not appear to provide sufficient enablement for any "anti-PSGL-1 antibody" that can induce apoptosis of T cells and NK cells in order to reduce cell-mediated immune responses
in the absence of administering secondary cross-linking agents / antibodies or in the absence of multivalent anti-PSGL-1 antibodies.

This invention encompasses any "anti-PSGL-1 antibody" to accomplish the claimed methods resulting in the induction of apoptosis of activated T cells (e.g. see Summary of the Invention, yet the instant specification does not provide sufficient direction and guidance as to the nature of antibodies that can induce apoptosis of activated T cells in the absence of cross-linking in vivo or in the absence of administering multivalent anti-PSGL-1 antibodies, broadly encompassed by the claimed invention.

While cross-linking antibodies in vivo may be accomplished by various antibody constructs, including multimeric antibodies, or whole antibodies that bind anti-PSGL antibodies that are not hamster antibodies,
the instant disclosure provides for insufficient guidance and direction towards the relevant, identifying characteristics of the "anti-PSGL-1 antibody that can induce apoptosis" in the absence of cross-linking via secondary agents / antibodies or by administering multivalent anti-PSGL-1 antibodies".

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe nor enable any "anti-PSGL-1 antibody" that can induce apoptosis in the absence of secondary cross-linking agents / antibodies or in the absence of administering multivalent anti-PSGL-1 antibodies.

Without sufficient guidance, making and using any "anti-PSGL-1 antibody" to induce apoptosis of activated T cells in the absence of administering the appropriate secondary cross-linking agent / antibody" or the use of multivalent anti-PSGL-1 antibodies in the claimed methods would have been unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Applicant's arguments have not been found persuasive.

7. Upon reconsideration of applicant's amended claims filed 10/26/2007, particularly the inclusion of the "selecting step",
the previous rejection under 35 U.S.C. § 102(b) as being anticipated by Larsen et al. (U.S. Patent No. 5,840,679) (see entire document) essentially for the reasons of record and in further evidence of Chen et al. (Blood 104: 3233-3242, 2004) has been withdrawn.

8. Upon reconsideration of applicant's amended claims filed 10/26/2007, particularly the inclusion of the "selecting step",
the previous rejection under 35 U.S.C. § 102(e) as being anticipated by Lazarovits et al. (US 2004/0002450 A1) and as further evidenced by the Lin 132 Declaration, filed 02/01/2007 has been withdrawn.

9. Upon reconsideration of applicant's amended claims filed 10/26/2007, particularly the inclusion of the "selecting step",
the previous rejection under 35 U.S.C. § 103(a) as being unpatentable over by Larsen et al. (U.S. Patent No. 5,840,679) in view of Trembleau et al. (J. Immunol. 163 : 2960 – 2968, 1999), Yago et al. (J. Immunol. 161 : 1140 –1145 (1998), Hirata et al. (J. Exp. Med. 192: 1669 – 1675, 2000) and Cobbold et al. (U.S. Patent No. 6,056,956)
and as futher evidenced by Chen et al. (Blood 104: 3233-3242, 2004) has been withdrawn.

10. Upon reconsideration of applicant's amended claims filed 10/26/2007, particularly the inclusion of the "selecting step",
the previous rejection under 35 U.S.C. § 103(a) as being unpatentable over by Larsen et al. (U.S. Patent No. 5,840,679) in view of Trembleau et al. (J. Immunol. 163: 2960 – 2968, 1999), Yago et al. (J. Immunol. 161 : 1140 –1145 (1998), Hirata et al. (J. Exp. Med. 192: 1669 – 1675, 2000) and Cobbold et al. (U.S. Patent No. 6,056,956)
and as futher evidenced by Chen et al. (Blood 104: 3233-3242, 2004) essentially for the reasons of record.
and further in view of Snapp et al. (Blood 91: 154-164, 1998) (1449; #AS) AND/OR Lazarovits et al. (US 2004/0002450 A1) (see entire document)
and as further evidenced by the Lin 132 Declaration, filed 02/01/2007 has been withdrawn.

11. Claims 1, 3, 4, 6, 11-13, 17, 19, 20, 22-25 and 38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 8, 9, 12-15, 19-22, 23, 26, 30, 31, 34-38 of copending application USSN 10/662,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same or nearly the same methods of preventing or reducing T cell-mediated immune responses with the same nearly the same PSGL-1-specific antibodies. Therefore, the copending claims either anticipate or render obvious one another.

It is noted that the copending claims recite a "multimeric compound that binds at least two PSGL-1 proteins". Given that the copending claims also recite "anti-PSGL-1 antibodies" and that antibodies have two binding sites, the copending claims appear to read on the instant claims drawn to the essentially the same methods relying upon PSGL-1 antibodies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3, 4, 6, 11-13, 17, 19, 20, 22, 23, 24 and 25 are directed to an invention not patentably distinct from claims 1, 4, 8, 9, 12-15, 19-22, 23, 26, 30, 31, 34-38 of commonly assigned USSN 10/662,906 for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned USSN 10/662,906, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Applicant's amendment, filed 10/24/2007 acknowledged the obvious double patenting rejection, but requests it to be held in abeyance until such time as the present or copending application issues into a patent.

12. No claim allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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